RESPONSE

The Office Action mailed May 5, 2004 has been carefully considered. Reconsideration in view of the following remarks is respectfully requested.

Claims 1-17 are currently pending. Claims 1-17 have been rejected. Claims 1 and 5 have been amended to further particularly point out and distinctly claim subject matter regarded as the invention. Support for these changes may be found in the specification on page 11 and 19. The text of claims 1-4 and 6-17 are unchanged, but their meaning is changed because they depend from amended claims.

Specification

The Office Action states:

> The use of the trademark "Actifoam™" and "Gelfoam" have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology. ... Applicants did not capitalize the trademarks in the specification."

Applicant has reviewed the specification and is unsure of where the trademark names have not been capitalized. Specifically, "Actifoam" is used only on page 12, line 6 and is capitalized. "Gelfoam" is used on page 4, line 1; page 30, line 5; and page 31, line 7 and is capitalized on those pages. It is respectfully requested that the Examiner point out the errors in the specification so that Applicant may make the proper amendment.

Claims 1-6, 8-13, 15 and 17 Rejection – 35 USC §102

Claims 1-6, 8-13, 15 and 17 stand rejected under 35 U.S.C. 102(e) as being allegedly anticipated by US PGPB 2002/0042378 (the '378 application). Claims 1 and 5 are independent claims. This rejection is respectfully traversed.

According to the M.P.E.P., a claim is anticipated under 35 U.S.C. § 102(a), (b) and (e) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.[1]

The office action states:

> "The present claim 1 recites composition comprising cross-linked gelatin and wetting agent. The claim recites the amount of wetting agent intended to permit wetting of gelatin in the presence of an aqueous solution. . . . claim 5 recites method for decreasing the hydration time of cross-linked gelatin composition comprises incorporating wetting agent with the gelatin prior to its hydration. . . .
>
> PGPB '378 disclosed hemoactive material or composition that is suitable for inhibiting bleeding, i.e. hemostatic, and are delivered to the target region in the tissue subject to bleeding (page 2: 0012; page 5:0039). The material comprises cross-linked biologically compatible polymer, non cross-linked biologically compatible polymer, and plasticizer (abstract; page 2:0016). The most preferred cross-linked polymer is gelatin (page 3:0031; page 5: example 2). The non cross-linked polymers include cellulose derivatives, polyvinyl polymers, and polyoxyethylenes; and the plasticizers include polyethylene glycol and sorbitol (page 2: 0016, 0018), all disclosed by applicant in the first full paragraph of page 9 of the instant specification as wetting agents. . . . Decreasing the hydration time of the cross-linked gelatin that [is] claimed in claim 5 is inherent in the material of the reference that comprises cross-linked gelatin and polyethylene glycol, and that has the wetting agent incorporated with the cross-linked gelatin prior to use and hydration."

The office action equates the non cross-linked polymer to the wetting agent of the present invention. Moreover, the office action equates the dissolution of the non cross-linked polymer to the hydration of the wetting agent of the present invention. Applicant respectfully disagrees for the reasons, among others, discussed below.

Claim 1

Amended Claims 1 and 5 provide for:

1. A biocompatible, hemostatic, cross-linked gelatin composition comprising a cross-linked gelatin foam and a sufficient amount of a liquid wetting agent to permit uniform wetting of the gelatin foam in the presence of an aqueous solution.

5. A method for decreasing the hydration time of a hemostatic cross linked gelatin composition which method comprises, prior to hydration of said cross-linked gelatin composition, incorporating a biocompatible liquid wetting agent with said cross-linked gelatin.

The non cross-linked polymer of the '378 application can not be equated to the wetting agent of the present invention.

The wetting agent of the present invention is incorporated into the gelatin to permit uniform wetting of the sponge in the presence of an aqueous solution to decrease the **hydration** time of the gelatin composition. (Specification, page 7, lines 20-23). The wetting agent, as defined in the specification, is to facilitate or enhance the **hydration** of a hemostatic sponge. (Specification 9, lines 3-4).

The '378 application specifically states that the "non-cross-linked polymer is chosen to **solubilize** relatively rapidly when exposed to blood. The non-cross-linked polymer serves as a binder for holding the materials in desired geometries, such as sheets, pellets, plus, or the like" (Abstract). As stated in the '378 application, the sheet of hemoactive material "immediately begins absorbing water from the blood present at the site. Within minutes, the non-cross-linked polymer component of the material will begin to **dissolve** and release the cross-linked particles." (page 5: 0040). Thus, the non-cross-linked polymer is to merely bind the cross-linked particles in a desired shape and to quickly **dissolve**, so that the cross-linked particles can form a hydrogel. The dissolution of the non cross-linked polymer is further pointed out in the application on page 2, 0013, 0019 and Page 5, 0040.

[1] Manual of Patent Examining Procedure (MPEP) § 2131. See also *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The dictionary definition of hydration is "to cause to take up or combine with water or the elements of water." (See Exhibit A). As stated in the specification, the wetting agents of the present invention attract, retain, and bind to the fluid and do not dissolve into the fluid. Rather, the dictionary definition of dissolve is "to cause to disperse or disappear". (See Exhibit B). As stated throughout in the '378 application, the non cross-linked polymer actually dissolves and disappears into the blood and is not retained within the cross-linked polymer to aid in hydration of the blood. Rather, the non cross-linked polymer is merely used to bind the cross-linked polymers together. As such, the non cross-linked polymer of the '378 application can not be equated with the wetting agents of the present invention.

<u>The non cross-linked polymer of the '378 application is in dry form whereas the wetting agent of the present invention is in aqueous form</u>

"The wetting agent can be added and dissolved (or dispersed) directly into the hemostat chemical formulation, preferably just before the foaming process." (Specification, page 11, line 11-13). The wetting agent is added to the chemical formation prior to the foam process in liquid form. This is further supported in the Examples provided, such as on page 19.

On the other hand, the '378 application states that the "cross-linked polymer is dispersed in a dried matrix of the non cross-linked polymer." (page 1, 0012). This is further stated throughout the specification of the '378 application and also in Claim 1 which states "the cross-linked polymer is dispersed in a **dried** matrix of the non-cross-linked polymer" and Claim 2 which states "**dry**, cross-linked gelatin polymer particles dispersed in the dry non-cross-linked gelatin matris." (page 7, Claim 1 and 2).

Thus, the '378 application teaches dispersing the non cross-linked polymer with the cross-linked polymer when both are in the dry phases and does not teach "a sufficient amount of a **liquid** wetting agent" as provided for in Claim 1 and similarly in Claim 5.

Accordingly, since each and every element as set forth in Claims 1 and 5 are not found, either expressly or inherently described, in the '378 application, it can not be said to anticipate the present invention. Thus, it is respectfully requested that this rejection be withdrawn.

Claim 16 Rejection – 35 USC §102

According to M.P.E.P. §2136.02, "[f]or applications filed on or after November 29, 1999, if the applicant provides evidence that the application and prior art reference were ... subject to an obligation of assignment to the same person, ... any rejections under 35 U.S.C. 102(e)/103 based upon such a commonly owned reference should not be made or maintained." See also, MPEP §706.02(II).

The office action states that "Claim 16 is rejected under 35 U.S.C. 102(e) as being anticipated by US PGPB 2003/0088271 ('271)." This rejection is respectfully traversed. '271 and the present application, were, at the time the invention was made, owned by, or subject to an obligation of assignment to the same entity, Sub-Q, Inc. The assignment for '271 is located on Reel/Frame 014738/0650 and the assignment for the present invention may be found in Reel/Frame 013007/0656. Accordingly, it is respectfully requested that this rejection be withdrawn.

Dependent Claims

The argument set forth above is equally applicable here. The base claims being allowable, the dependent claims must also be allowable.

Request for Allowance

It is believed that this Response places the above-identified patent application into condition for allowance. Early favorable consideration of this application is earnestly solicited.

If, in the opinion of the Examiner, an interview would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney at the number indicated below.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Please charge any additional required fee or credit any overpayment not otherwise paid or credited to our deposit account No. 50-1698.

Respectfully submitted,
THELEN REID & PRIEST, LLP

Dated: June 30, 2004

Adrienne Yeung
Reg. No. 44,000

THELEN REID & PRIEST LLP
P. O. Box 640640
San Jose, CA 95164-0640
Tel: (408) 292-5800
Fax: (408) 287-8040